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STN	**Zariadenia s krátkym dosahom (SRD) Bezdrôtové lekárske zariadenia veľmi nízkeho výkonu (ULP) pre kapsulovú endoskopiu pracujúce v pásme od 430 MHz do 440 MHz Harmonizovaná norma pre prístup k rádiovému spektru**	**STN EN 303 520 V1.1.1** 87 3520

Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.1] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.2].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in Table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

National transposition dates	
Date of adoption of this EN:	17 July 2018
Date of latest announcement of this EN (doa):	31 October 2018
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 April 2019
Date of withdrawal of any conflicting National Standard (dow):	30 April 2020

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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Introduction

The present document is aiming to cover radio and telecommunications terminal equipment within the scope of the EU's Radio Equipment Directive (RED) [i.2].

The present document specifies conformance requirements for the Ultra Low Power Wireless Medical Capsule Endoscopy SRD application, which includes Capsule Camera (CCam) acting as transmitter and associated Data Recorder (DR) receiver devices, as meant by ETSI TR 103 451 [i.3]. The CCam is designed to wirelessly transmit recorded images from inside patient's gastrointestinal tract to the DR receiver, utilizing a single wideband radio channel occupying the entire designated band 430 MHz to 440 MHz. It is intended that this band will be harmonised for European-wide usage by Ultra Low Power Wireless Medical Endoscopy application through relevant CEPT and EU normative documents in the field of SRD spectrum regulation, such as CEPT/ERC/REC 70-03 [i.4].

CCam transmitters will utilize miniature integral antenna encapsulated within its pill-shaped enclosure. The intended use of the CCam transmitter is inside the human body.

DR receivers will use either integral antenna or dedicated external antenna implemented in the form of skin patch or belt. Such dedicated external antenna would ensure optimal reception of weak radio signals by keeping antenna in direct proximity to the patient's body in the area closest to internal passage of CCam.

These devices would offer opportunity of performing medical endoscopy-type examination of the entire human gastrointestinal tract including the small intestine and colon. Thanks to simple application with minimized risks and side effects, while providing the unique ability to visualize the complete gastrointestinal tract, its use would be highly beneficial and attractive to patients and doctors.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms, symbols and abbreviations used.
- Clause 4 specifies the requirements and limits applicable to CCam transmitter and DR receiver.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Clause 5.3 specifies the methods of measurement for the parameters specified in clause 4.
- Annex A (informative) provides an overview of the relationship between the present document and the essential requirements of the RED [i.2].
- Annex B (normative) describes a human torso simulator test fixture to be used for radiated measurements.
- Annex C (normative) describes the Full Anechoic Room test site configuration for radiated measurements.

1 Scope

The present document specifies technical characteristics and methods of measurements for Ultra Low Power Wireless Medical Capsule Endoscopy application (CCam transmitters and associated DR receivers) operating in the designated frequency band 430 MHz to 440 MHz, as meant by ETSI TR 103 451 [i.3].

A possible return (downlink) RF transmission channel from DR to CCam for command and control signalling, if and when implemented, will be outside the scope of the present document.

NOTE: The relationship between the present document and essential requirements of article 3.2 of Directive 2014/53/EU [i.2] is given in Annex A.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version applies.

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Not applicable.

2.2 Informative references

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The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED).

[i.3] ETSI TR 103 451: "System Reference document (SRdoc); Short Range Devices (SRD); Technical characteristics for UHF wideband Ultra Low Power Wireless Medical Capsule Endoscopy".

[i.4] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.5] Body Tissue Dielectric Parameters. Reference Calculation Tool provided by the Federal Communications Commission.

NOTE: Available online at: https://www.fcc.gov/general/body-tissue-dielectric-parameters.

[i.6] Hartsgrove, G., Kraszewski, A. & Surowiec, A. (1987): "Simulated biological materials for electromagnetic radiation absorption studies". Bioelectromagnetics, 8(1), 29-36.